ORİJİNAL ARAŞTIRMA ORIGINAL RESEARCH

Comparison of the Efficacy of High Intensity Laser and Ultrasound Therapies in Chronic Shoulder Pain; Randomized Controlled Single Blind Study

Kronik Omuz Ağrısında Yüksek Yoğunluklu Lazer ve Ultrason Tedavilerinin Etkinliklerinin Karşılaştırılması; Randomize Kontrollü Tek Kör Çalışma

Burcu METİN ÖKMEN,[a]
Korgün ÖKMEN,[b]
Kağan ÖZKUK,[c]
Bilal UYSAL,[d]
Refia SEZER,[d]
Engin KOYUNCU[e]

Clinics of
[a]Physical Medicine and Rehabilitation,
[b]Anesthesiology and Reanimation,
Health Sciences of University,
Bursa Yüksek Ihtisas Training and
Research Hospital, Bursa
Clinics of
[c]Medical Ecology and Hydroclimatology,
[d]Physical Medicine and Rehabilitation,
Abant İzzet Baysal Physical Medicine
and Rehabilitation Training and
Research Hospital, Bolu
[e]Physical Medicine and Rehabilitation,
Health Sciences of University,
Ankara Physical Medicine and
Rehabilitation Training and
Research Hospital, Ankara

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Yazışma Adresi/*Correspondence:*
Burcu METİN ÖKMEN
Health Sciences of University,
Bursa Yüksek Ihtisas Training and
Research Hospital,
Physical Medicine and Rehabilitation,
Bursa,
TURKEY/TÜRKİYE
burcumetinokmen@gmail.com

ABSTRACT Objective: The aim of our study was to compare the efficacy of the High Intensity LASER Therapy (HILT) and Ultrasound (US) for pain and daily activities of patients with chronic shoulder pain. **Material and Methods:** In this prospective, randomized, controlled, single blind study; 141 patients were randomized into two groups by using random table, as Group 1: US (n=70) and Group 2: HILT (n=71). HILT or US treatment was applied to the patients in addition to 14 sessions of Hotpack in (HP) +Transcutaneous Electrical Nerve Stimulation (TENS) +Balneotherapy + Exercise. Pre-treatment (W0), Post-treatment 1st day (W2) and Post-Treatment findings 30th day (W6) findings were recorded using the visual analog scale (VAS) and shoulder pain and disability index (SPADI) scoring. **Results:** There were no statistically significant difference neither in demographic characteristics nor pretreatment evaluation parameters between the two groups ($p>0.05$). In Group 1 and Group 2, statistically significant improvements were found in all the evaluation parameters both at W2 and W6 ($p<0.05$). When the groups are compared to each other; statistically significant difference was found in favor of Group 2 both at W2 and W6, in all evaluation parameters ($p<0.05$). **Conclusion:** This study demonstrates that in chronic shoulder pain HILT is superior to US therapy in decreasing pain and improving function in short term.

Key Words: Shoulder pain; chronic pain; laser; ultrasound; rehabilitation; physical therapy modalities

ÖZET Amaç: Çalışmamızın amacı, kronik omuz ağrısı olan hastalarda Yüksek Yoğunluklu Lazer Tedavisinin (HILT) ve Ultrasonun (US) ağrı ve günlük aktiviteler üzerine etkinliğini karşılaştırmaktı. **Gereç ve Yöntemler:** Bu prospektif, randomize, kontrollü, tek kör çalışmada; 141 hasta rastgele tablosu kullanılarak Grup 1: US (n=70) ve Grup 2: HILT (n=71) olmak üzere iki gruba randomize edildi. Hastalara 14 seans Hotpack (Hp) + Transkutanöz Elektriksel Sinir Uyarısı (TENS) + Balneoterapi + Egzersiz tedavisine ek olarak HILT veya US tedavisi uygulandı. Görsel Analog Skala (VAS) ve omuz ağrısı ve özürlülük indeksi (SPADI) skorlaması kullanılarak tedavi öncesi (H0), tedavi sonrası 1. gün (H2) ve tedavi sonrası 30. gün (H6) bulguları kaydedildi. **Bulgular:** İki grup arasında demografik özellikler ve tedavi öncesi değerlendirme parametrelerinde istatistiksel olarak anlamlı farklılık yoktu ($p>0,05$). Grup 1 ve Grup 2'de hem H2 hem de H6'daki tüm değerlendirme parametrelerinde istatistiksel olarak anlamlı düzelmeler bulundu ($p<0,05$). Gruplar birbirleriyle karşılaştırıldığında; Grup 2'nin lehine hem H2 hem de H6'da tüm değerlendirme parametrelerinde istatistiksel olarak anlamlı fark bulundu ($p<0,05$). **Sonuç:** Bu çalışma, kronik omuz ağrısında HILT'in kısa vadede ağrıyı ve fonksiyonu iyileştirmede US tedavisinden daha üstün olduğunu ortaya koymaktadır.

Anahtar Kelimeler: Omuz ağrısı; kronik ağrı; lazer; ultrason; rehabilitasyon; fizik tedavi modaliteleri

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Chronic shoulder pain, which negatively affects the quality of life due to pain and loss of functions, is the third most common painful condition of the musculoskeletal system.[1] Shoulder pain affects 7-36%

of society.[2] The range of motion of the joints (ROM) is limited in many patients due to pain and this limitation in turn may restrict activities in daily life.[3,4]

While the most commonly seen causes of shoulder pain are rotator cuff pathologies and impingement syndrome, some degenerative diseases, such as frozen shoulder, calcific tendinitis and osteoarthritis (OA) are also among the etiologic reasons of chronic shoulder pain.[5,6]

Analgesics and nonsteroidal anti-inflammatory drugs (NSAID), steroid injections, physical therapy (PT) methods, exercise and surgical procedures have been used in the treatment of chronic shoulder pain. Pain resolution and preservation of functions are the main principles of physical medicine and rehabilitation (PMR). Ultrasound (US), LASER, Manual Therapy, Extracorporeal Shock Wave Therapy (ESWT), Interferential Direct Current, and Acupuncture are frequently used for this reason.[7]

Therapeutic US is commonly used in the treatment of shoulder pathology and is generally prescribed in conjunction with other interventions. When applied at an appropriate intensity and frequency, it increases the temperature in soft tissues with a high protein density. The physiological effects of therapeutic US are increased blood flow, vascular permeability, and local metabolism and improved fibrous tissue extensibility and muscle relaxation.[8-10]

LASER, a relatively newer option of treatment compared with US, which has been used since 1960s, has developed over time. Recently introduced, High Intensity LASER Therapy (HILT) might affect a larger area and a deeper thickness of the tissues compared with the more commonly used Low Level Laser Therapy (LLLT). Treatment using HILT is through mitochondrial oxidative reaction and increased production of adenosine triphosphate, DNA and RNA (photobiology effect). Its pain resolution effect on the other hand is provided by decreased pain stimuli and increased morphine-mimetic elements.[11]

In the literature we have found only one study comparing the efficacy of HILT and US in chronic shoulder pain.[7] Therefore we aimed to compare the superiority of HILT and US treatments, which are frequently used in our clinic, to each other for pain and daily activities of patients with chronic shoulder pain which was difficult to treat.

MATERIAL AND METHODS

This prospective, randomized, controlled, single blind study was conducted at the Physical Medicine and Rehabilitation Training and Research Hospital and ethics board approval was obtained. The decision number is 2015/46. The study was conducted in accordance with the principles of Declaration of Helsinki.

PATIENTS

A total of 210 patients, who presented to our hospital with chronic shoulder pain, were evaluated for inclusion in the study. Inclusion criterias were 1) to be between 35-75 years old 2) the presence of shoulder pain for more than 3 months. We included only the patients who had impingement syndrome into our study. Physical examination and shoulder examination (Hawkins' Test, Drop Arm Test, Neer Test, Painful Arc Test, Yergason Test, etc.), were conducted on the patients. Laboratory tests were ordered, imaging modalities X-Ray, MRI and US were used to make the definitive diagnosis. Exclusion criteria were 1) adhesive capsulitis 2) receiving PT and injection treatment to the same shoulder region in the previous year, 3) Malignancy, 4) The presence of radicular pain and cervical myofascial pain syndrome, 5) a history of acute trauma, 6) a prior history of fracture in the shoulder to be treated, 7) a prior history of surgical intervention and implantation of a metal implant to the affected shoulder, and 8) inflammatory rheumatoid disease.

Among the 210 patients; 56 patients were excluded from the study (Figure 1). 154 patients were re-evaluated by the investigating physician. Physical examination and shoulder examination (Hawkins' Test, Drop Arm Test, Neer Test, Painful

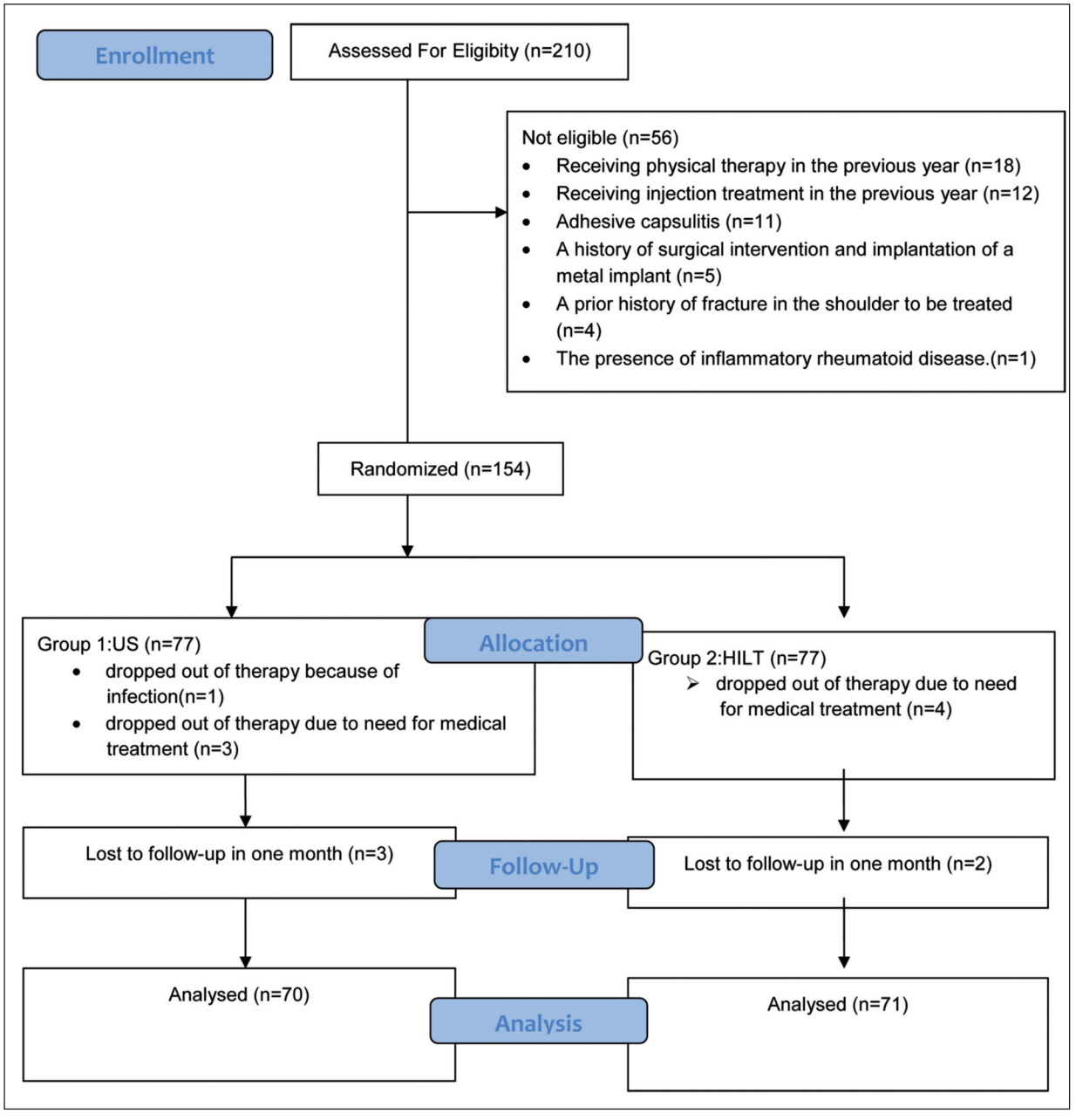

FIGURE 1: Flow diagram of recruitment and retention for Ultrasound Therapy and High Intensity LASER Therapy for chronic shoulder pain.

Arc Test, Yergason Test, etc.), were conducted on the patients by the same investigating physician. Laboratory tests were ordered, imaging modalities X-Ray, MRI and US were used to make the definitive diagnosis. Patients were informed about the study. Patients who agreed to be volunteers in the study signed informed consent forms. Patients were expressly told not to use any analgesics and NSAID during and after treatment.

RANDOMIZATION

Patients were randomized into two groups by the investigating physician, using random table, and their treatment was organized.

INTERVENTIONS

Patients who were randomly divided into two groups received treatment for two weeks (14 days) are shown below:

Group1: Hotpack (HP) +Transcutaneous Electrical Nerve Stimulation (TENS) + Balneotherapy + Exercise + US

Group2: HP + TENS + Balneotherapy + Exercise + HILT

Patients in both groups received HP and TENS to the affected shoulder region for 20 minutes and balneotherapy, in mineral water pool at 38-40^{0}C for 20 minutes, for 14 consecutive days. ROM exercises and Codman exercises, in a level not to increase the severity of the pain of the patient, were given and stretching and strengthening exercises were taught to the patients. They performed these exercises daily in two sets with five repeats in each set under the supervision of an experienced physiotherapist while taking their treatments. It was especially emphasized that they should do them regularly after discharge from the hospital. Patients were questioned whether they were doing their exercise when they came to the controls and we determined that they were doing them regularly.

HILT was performed using a BTL-6000 High Intensity LASER, 12 W (watt), 1064 nm device was a hot laser with Nd: YAG LASER source. In HILT group, we applied the device on the shoulder area in two phases: phase I, and phase II. Current at phase I mode for 2 sessions every other day (a total of 4 days) was transmitted primarily to decrease patient pain. Phase I mode was applied with pulsed mode at 1064 nm wave length and 8 W power for 250 seconds with a frequency of 25 Hz, so that it was 20 j/cm^2 at total dose of 500 j (area of 25 cm^2). After phase I mode sessions were completed, the current was applied at phase II mode for 5 sessions again every other day (a total of 10 days). It was applied at 1064 nm wavelength and 7 W power for 357 seconds no frequency with continuous mod, so that it was 100 j/ cm^2 at total dose of 2500 j (area of 25 cm^2). In both phase I and phase II mode, the application was made by using continuous circular movements. The surface of applied headpiece was 30 mm and 3.14 cm^2. A standard headpiece endowed with fixed spacers was used to provide the same distance to the skin. Protective glasses were used to protect eyes by both the patient and the person applying HILT.

BTL 4710 US device was applied at 3 MHz frequency, and 1.5watt/cm^2 intensity over 25 cm^2 surface area. Headpiece area of the device was 5 cm^2, and the application was performed as the head of device was positioned at 90^o (perpendicular) at full contact for 5 minutes by using gel, and performing continuous circular motions. US applied to the patients for 14 consecutive days.

Forms detailing the patients' demographic characteristics and pre-treatment (W0) tests were completed by another investigating physician who was blind to the type of treatment the patients received. The same investigating physician completed Post-treatment 1st day (W2) and Post-Treatment 30th day (W6) forms and recorded the data.

EVALUATION PARAMETERS

Patients were evaluated using Visual Analog Scale (VAS) for pain and Shoulder Pain And Disability Index (SPADI) in W0, W2 and W6.

VAS is a frequently used test worldwide, for which reliability studies have been performed.[12]

SPADI was developed to measure shoulder discomfort. Its evaluation includes two parts: pain and disability. Part 1 includes five questions in the pain subgroup and measures the pain experienced by the patient over the previous week using VAS (0 no pain, to 10, most severe pain). Part 2 is the disability subgroup and includes eight questions and measures the degree of difficulty (0 no difficulty, to 10, requires help) in the movements of the patient during the last week. SPADI includes 13 questions, and zero point refers to maximal well-being and 130 points refers to maximal sickness. We evaluated each part of the SPADI; shoulder pain index (SPI), shoulder disability index (SDI) and total SPADI separately. Validity of SPADI was demonstrated.[13] The Turkish version of the validity and reliability evaluation study for SPADI was implemented by Bicer et al.[14]

STATISTICAL ANALYSIS

Analysis of the collected data was performed using IBM SPSS 21.0 statistical package program. When the study data were evaluated, the Pearson chi square (c^2) or Yates c^2 tests were used in the comparison of the qualitative variables, in addition to descriptive statistical methods (frequency, percentage, mean and standard deviation). Normal distribution of the data was tested using Kolmogorov-Smirnov test. Independent Samples t test (t test for independent groups) was used in between-groups comparisons and paired sample t-test was used in intra-group comparisons. Values with a probability of (P) a< 0,05 was accepted as significant.

Power Analysis: Post-hoc power analysis was performed using G*Power 3.0.10 statistical package program and n_1=70, n_2=71, α=0,05, d (Effect size)= 0,5 and power (1-β)=0,84.

TABLE 1: Comparison of the demographic characteristics, affected size, and duration of pain between groups.

	Group 1 (n=70)	Group 2 (n=71)	p
Age (year)	59.5 ± 9.8	57.4 ± 9.3	0.197
Gender			
Female	47 (%67.1)	49 (%69.0)	0.954
Male	23 (%32.9)	22 (%31.0)	
Affected site			
Left	30 (%42.9)	25 (%35.2)	0.352
Right	40 (%57.1)	46 (%64.8)	
Durations of pain (month)	16.6 ± 16.7	14.7 ± 16.8	0.487

Group 1: Ultrasound Therapy Group 2: High Intensity LASER Therapy.

RESULTS

During the treatment and follow-up period of 154 patients, one patient was excluded from the study due to a newly developed infection in the foot, seven patients due to need for medical treatment, and five patients due to drop out of the follow-up (Figure 1). The study was completed with 141 patients, 71 of whom were in the HILT group and 70 in the US group. There was no statistically significant difference in demographic characteristics and pretreatment evaluation parameters between the two groups (p>0.05) (Table 1, 2).

In Group 1 and Group 2, statistically significant improvements were found in all the evaluation parameters both immediately after treatment

TABLE 2: Comparison of the VAS and SPADI values in W0, W2 and W6 within the groups and between the groups.

	W0	W2	W6	P**(W2-W0)	P**(W6-W0)
VAS					
Group 1(n=70)	68.57±18.73	54.87±16.45	41.93±13.99	<0.001	<0.001
Group 2(n=71)	65.94±15.67	46.37±17.26	26.58±13.10	<0.001	<0.001
P*	0.368	0.003	<0.001		
SPADI					
SPI					
Group 1(n=70)	36.14±9.44	28.44±9.03	23.39±8.04	<0.001	<0.001
Group 2(n=71)	34.44±10.20	25.23±8.78	15.48±7.24	<0.001	<0.001
P*	0.304	0.034	<0.001		
SDI					
Group 1(n=70)	49.24±16.52	39.26±14.77	32.53±13.02	<0.001	<0.001
Group 2(n=71)	45.07±17.94	33.20±14.54	21.14±11.49	<0.001	<0.001
P*	0.153	0.015	<0.001		
Total					
Group 1(n=70)	85.39±24.21	67.70±21.90	55.91±18.67	<0.001	<0.001
Group 2(n=71)	79.51±25.41	58.42±20.30	36.62±16.46	<0.001	<0.001
P*	0.162	0.010	<0.001		

*Between groups, ** Within groups W0: Pre-treatment, W2: Post-treatment 1st day, W6: Post-treatment 30th day.

Group 1: Ultrasound, Group 2: High Intensity LASER Therapy,

VAS: Visual analog skala, SPADI: Shoulder pain and disability index, SPI: Shoulder pain index, SDI: Shoulder disability index.

TABLE 3: Comparison of the percentage of the change scores in VAS and SPADI between the groups.

	W2-W0	W6-W0
VAS		
Group 1 (n=70)	-20.44±8.82	-39.18±10.41
		-61.12±12.84
Group 2 (n=71)	-31.00±15.46	<0.001
p*	<0.001	
SPI		
Group 1 (n=70)	-22.08±9.79	-35.39±12.97
		-55.00±16.15
Group 2 (n=71)	-27.09±12.16	
p*	0.008	<0.001
SDI		
Group 1 (n=70)	-20.69±10.71	-34.15±13.17
Group 2 (n=71)	-26.15±11.39	-53.34±13.39
p*	0.004	<0.001
SPADI		
Group 1 (n=70)	-21.36±7.80	-35.03±7.63
Group 2 (n=71)	-26.44±9.02	-54.23±11.82
p*	<0.001	<0.001

Mean±SD *Between groups W0: Pre-treatment, W2: Post-treatment 1st day, W6: Post-treatment 30th day.
Group 1: Ultrasound, Group 2: High Intensity LASER Therapy, VAS: Visual analog skala, SPADI: Shoulder pain and disability index, SDI: Shoulder disability index, SPI: Shoulder pain index.

(W2) and 4th week after treatment compared to their initial values (W6) ($p < 0.05$) (Table 2).

When the groups are compared to each other; statistically significant difference was found in favor of Group 2 both at after treatment (W2) and 4th week after treatment (W6), in all evaluation parameters ($p < 0.05$) (Tablo 2, 3).

DISCUSSION

In this study, in both US and HILT group significant improvement was obtained in pain, functionality and daily life activities in patients with chronic shoulder pain at both W2 and W6. But we also found that improvement in pain and functions of patients was better in the HILT group.

US as a PT modality, is still accepted as an effective therapy and continues to be the subject of investigations and discussions. In many studies, however, authors reported equivocal opinions on the efficacy of US as a PT agent.[9,15,16] In a study by Ainsworth et al, which is one of the studies reporting a negative opinion on the use of US, 200 patients with shoulder pain were evaluated. A group of patients treated with exercise + manual therapy, and patients treated with exercise + US were compared. No significant difference was found in the group of patients who were applied US between Pre-Treatment and Post-Treament.[16] In another study with similar results, Kurtais et al. compared US and placebo US in a patient group that was applied HP, TENS and Exercise. Although improvements were determined in the ROM, Health Assessment Questionnaire*(*HAQ) and Shoulder Disability Questionnaire (SDQ) scores, there was no significant differences between the two groups.[9] Some other authors, on the other hand, suggested that US was effective when used in addition with other PT agents.[17-20] Perez Merino et al. compared three groups in which they applied US, Phonophoresis and Iontophoresis in addition to Exercise + Cryotherapy in patients with the diagnosis of subacromial impingement and they determined that US was more effective.[20] Yavuz et al., in a study in which they reached similar results, compared 2 groups in which they applied US and LLLT in addition to Exercise + HP in patients with subacromial impingement. Although they found US more effective, they suggested that LLLT might also be used in cases where US was contraindicated.[17] As a result of our study we observed that US, when applied in addition to HP +TENS+ Balneotherapy + Exercise treatment in chronic shoulder pain, is effective and this positive effect continues at the end of the first month. The clinical results of this study were similar to the results of the study performed by Yavuz F et al. and Perez Merino et al, and demonstrated that US was a beneficial adjuvant therapy in patients with chronic shoulder pain.[17,20] The reasons for the better results in this study compared with the studies performed by Giombini et al, Ainsworth et al and Kurtais et al might be due to the differences in the additional PT that we had performed (HP – TENS-Balneotherapy– Exercise).[9,15,16]

Equivocal results of the use of US as a treatment option resulted in alternative treatment options. LASER therapy has been used as one of those modalities. Both types of LASER treatment, LLLT has been used for a longer time than HILT. LLLT

has been used in the treatment of shoulder disorders and was detected to have better results as an adjunctive treatment option and had beter functional results.[21-23] Literature findings on the efficacy and field of application of HILT, which has been introduced relatively recently, compared with LLLT are limited. Several studies on HILT in the literature for painful conditions of the shoulder, myofascial pain syndrome, tendinopathies, back pain and knee OA, are available.[7,24-28] In the study by Alayat et al, 72 male patients with back pain were divided into three groups as HILT + Exercise, Placebo + Exercise and only HILT treatment. The most effective results were acquired in the HILT + Exercise group.[25] In another study evaluating the efficacy of HILT, the best results were obtained in the group with myofascial pain in the trapezius muscle, receiving HILT together with exercise.[27] In study by Dundar et al., they concluded with better results in the group in which HILT treatment was added in the treatment of lateral epicondylitis.[24] Although the studies discussed above and other studies reviewed in the literature are not on shoulder region, their common finding is that more successful results are obtained using HILT.[7,24-28] There are a limited number of studies in the literature on the use of HILT in shoulder pain.[7,28] Among those studies, was a prospective, randomized controlled study, in patients with frozen shoulder, performed by Kim et al., in which 66 patients were randomized into two groups each comprising 33 patients. The first group received HILT+ Exercise and the second group received Placebo + Exercise. In the VAS score, which was 6.2 ±1.7 in the HILT + Exercise group was 3.2±1.7 in the third week, and 2.2±2 in the eighth week, the improvement was found to be statistically significant compared with the Placebo + Exercise group. They found no statistically significant difference in the VAS and ROM values in the twelfth week. They suggested that HILT was a non-invasive treatment option that could be added to the exercise program with the aim of providing pain control.[28] In this present study VAS scores in the group in which HILT was applied were found to be 6.26±1.9, 2.5±1.5, and 1.6±1.8 at W0,W2 and W6 respectively. These results were statistically significantly different compared to the W0 values; however, they were similar to the results that Kim et al. had obtained although the measurements were performed in different time points in this present study. The results of SPADI were more effective compared with the VAS scores during ROM in Kim et als' study.[28] This difference we had detected could be due to the different PT agents we had used together with HILT.

In a prospective randomized study that includes similarities with the present study, the authors had compared the efficacy of HILT and US treatment in two different groups. They recorded pre-Treatment and post-Treatment VAS, Constant-Murleyscore (CMS) and Simple Shoulder Test (SST) scores. There was no difference between the groups in CMS and SST values. Values were statistically significantly lower in the HILT group. The authors reported that this decrease in the VAS score was promising for HILT.[7] We also found a decrease in VAS scores in both the US and HILT groups, but this decline was more pronounced in the HILT group. The results of the HILT group reflect a positive effect on healing, similar to a small number of other studies.[7,28] In contrast to the two studies evaluated, the low values of SPADI that we had observed demonstrate that HILT provides more resolution between daily life activities and pain. Our primary goal was to compare the treatment effects of US and HILT and we found that HILT had a statistically significantly positive effect on treatment. One of the remarkable findings was that, VAS and SPADI values in the HILT group were still decreasing at W2 and W6 and the decrease was statistically significant.

HILT contains high intensity laser radiation and causes slow light absorption. This absorption is not with concentrated light, but with diffuse light (scattering phenomenon) in every direction. This suggests that it is effective on a wider surface.[11] It has been reported that HILT rapidly reduces pain and inflammation.[29] Additionally it has also been reported that can rapidly induce photochemical and photothermic effects that increase blood flow, cell metabolism and vascular permeability.[30] For this reason, we believe that HILT is more effective

in our study by spreading to a wider area and reaching deeper tissues. We also think that with rapid action, inflammation and pain are reduced more effectively than US and thus provides more significant improvement in patients.

LIMITATIONS OF THE STUDY

We consider that the weaknesses of this present study were the absence of a placebo control group and long-term follow-up results.

CONCLUSION

Although both HILT and US treatment are effective with additional PT agents in chronic shoulder pain, this study demonstrates that HILT treatment is superior to US in improving pain and function in the short term. But in order to clarify whether this effect continues in the long-term, studies with a longer follow-up, including placebo groups, are needed.

Conflicts of Interest

The authors have no conflicts of interest in regard to this research or its funding.

Authorship Contributions

Both authors have read and approved the manuscript and take full responsibility for its content.

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